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| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | LEE, SHUN K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 2878 | |

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,457

Applicant(s)

CASPERSEN, CHRISTIAN

Examiner

Shun Lee

Art Unit

2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 7. 6) ☐ Other: _____

DETAILED ACTION

National Stage Application

1. The Examiner acknowledges consideration of the International Preliminary Examination Report in International Application PCT/DK99/00515. MPEP § 1893.03(e).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.437 and PCT Rule 11.13(I) because they include the following reference sign(s) not mentioned in the description: 2, 5, 7, and 8. See MPEP § 1825. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1, 5, 6, 10, 29, 34, and 36 are objected to because of the following informalities:
 - (a) in claim 1, "objects" on line 12 should probably be --object--;
 - (b) in claim 5, "one or more light beams" on line 2 should probably be --at least a first light beam--;
 - (c) in claim 5, "objects" on line 3 should probably be --object--;
 - (d) in claim 6, "one or more" on line 2 should probably be --two or more--;
 - (e) in claim 10, "signals" on line 2 should probably be --detector signals-- (see for example "the detector signals" in claim 11);
 - (f) in claim 29, "objects" on line 5 should probably be --object--;

- (g) in claim 29, "member" on line 6 should probably be --member,--;
- (h) in claim 34, "form" on line 1 should probably be --from--; and
- (i) in claim 36, "properly" on line 3 should probably be --property-- (see original claim 36).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 29 recite the limitation "at least a first light beam" which was not described in the specification. In addition, claim 1 also recites the limitation "at least a first light source" which was not described in the specification (it has been noted that the International Preliminary Examination Report in International Application PCT/DK99/00515 indicates the amended claims fail to comply with PCT Article 34(2)(b)).

6. Claims 6 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification discloses (first two paragraphs on pg. 12) that in a single scan, "each marker may be detected by a separate detector". Independent claims 1 and 29 recite the limitation "two or more fluorescent markers". Thus claims 1 and 29 (and dependent claims) require two or more separate detector. However, dependent claim 6 recites the limitation "one detector is adapted to detect light emitted from each marker excited by the one or more light sources in a single scan" and dependent claim 34 recites the limitation "detecting light emitted from each marker excited by the one or more light sources in a single scan by one detector" which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "the scanning means" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 7-14, 17, 18, 23-31, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 5,892,577) in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967).

In regard to claims 1-3, Gordon discloses (Figs. 1, 3, and 6) an apparatus for detecting a property of an object contained in a specimen, the apparatus comprising:

- (a) a frame (6, 45, 47, 48),
- (b) a member (1, 18, 44) positioned on the frame (6, 45, 47, 48) and having a surface that is adapted to receive and hold the specimen (column 9, lines 51-55),
- (c) at least a first light source (*e.g.*, single light source 8, 19, 52) for emission of at least a first light beam (9, 20) towards the specimen held by the member (1, 18, 44),
- (d) at least one detector (*e.g.*, one detector 11, 38 or two or more detectors D1, D2, D3) for detection of light emitted (column 9, lines 51-55) from the object upon interaction with the at least first light beam (9, 20), and
- (e) scanning means (column 5, lines 37-43) for scanning the at least first light beam in relation to the at least one detector (11, 38, D1, D2, D3) across the specimen along a non-linear curve.

While Gordon also discloses (column 1, lines 5-99) assays or visualization with fluorescence labeling techniques (where specimen objects are stained with fluorescent markers), the apparatus of Gordon lacks an explicit example of two or more fluorescent

markers. However, fluorescence labeling techniques are well known in the art. For example, Ekins *et al.* teach (abstract and summary and conclusions) that "ratiometric" immunoassay involves measuring fluorescents emitted by two labels using laser scanning techniques closely analogous to those used in compact disk techniques. Therefore it would have been obvious to one having ordinary skill in the art to stain with two or more fluorescent markers in the apparatus of Gordon, in order to perform assays such as a "ratiometric" immunoassay.

In regard to claims **29-31**, the method steps are implicit for the apparatus of Gordon since the structure is the same as the applicant's apparatus of claims 1-3.

In regard to claim **7** (which is dependent on claim 1) and claim **35** (which is dependent on claim 29), Gordon also discloses (column 5, lines 37-42) that the member is positioned for rotation about an axis on the frame and the scanning means comprise means for rotating the member about the axis.

In regard to claims **8** and **9** which are dependent on claim 1, Gordon also discloses (column 5, lines 37-42) scanning control means (e.g., 41, 49 in Fig. 6) controlling the scanning means for scanning the specimen along a predetermined curve and that the scanning control means are adapted to control the scanning means in such a way that the predetermined curve is a substantially circular curve.

In regard to claim **10** (which is dependent on claim 8) and claim **36** (which is dependent on claim 29), Gordon also discloses (column 5, lines 58-62) storage means for storage of signals (related to the detected property) provided by the detector (e.g.,

11) and corresponding position signals (related to the current position of the member) provided scanning control means.

In regard to claim **11** (which is dependent on claim 8) and claim **37** (which is dependent on claim 36), Gordon also discloses (column 8, lines 15-27) means for sampling and digitizing the detector signals and the position signals.

In regard to claim **12** which is dependent on claim 1, Gordon also discloses (column 5, lines 58-62; column 6, lines 4-10 and 19-32; column 7, line 55 to column 8, line 27) signal processing means operatively connected to the detector to detect a presence of an object based on the detector signals.

In regard to claim **13** which is dependent on claim 12, Gordon also discloses (column 5, lines 58-62; column 6, lines 4-10 and 19-32; column 7, line 55 to column 8, line 27) that position signals relating to detected objects are stored in the storage means.

In regard to claim **14** which is dependent on claim 13, Gordon also discloses (column 5, lines 58-62; column 6, lines 4-10 and 19-32; column 7, line 55 to column 8, line 27) that the stored positions of the detected objects are retrieved, and used by said scanning means to position a means for optical inspection of detected objects (*i.e.*, "look again at specific region of interest"; column 6, lines 4-10).

In regard to claim **17** which is dependent on claim 1, Gordon also discloses (column 10, lines 16-18) that the scanning means further comprise deflecting means for scanning the first light beam across the specimen along a radius of the circular movement of the member.

In regard to claim **18** which is dependent on claim 1, Gordon also discloses (Fig. 6) that the light source (52) positioned rotation about an axis on the frame (45, 47, 48) and the scanning means comprise means (48) rotating the light source (52) about the axis.

In regard to claim **23** which is dependent on claim 1, Gordon also discloses (column 8, lines 28-43; Fig. 3) that a mask is inserted in the optical path between the specimen and the detector (D3), and the mask comprised at least one transparent aperture (53).

In regard to claims **24** and **25** which are dependent on claim 23, the apparatus of Gordon lacks that the aperture shape is a substantially rectangular shape and that at least one dimension of the aperture, as projected on the specimen, is between 0.75 and 2 times the dimensions of objects to be detected. Ekins *et al.* teach (left column on pg. 1964) that the highest signal/noise ratio is observed when the instrument field of view is restricted the microspot area. Therefore it would have been obvious to one having ordinary skill in the art to restrict the field of view with the aperture in the apparatus of Gordon to substantially the microspot area (*i.e.*, matching size and shape), in order to perform a "ratiometric" immunoassay with a desired signal/noise ratio.

In regard to claim **26** which is dependent on claim 1, the apparatus of Gordon lacks that one of the two or more fluorescent markers is Fluorescein. However, fluorescent markers such as fluorescein are well known in the art. For example, Ekins *et al.* teach (left column on pg. 1965) that fluorescein fluorescent markers (*e.g.*, FITC) are commercially available. Therefore it would have been obvious to one having

ordinary skill in the art to stain with two or more fluorescent markers (e.g., fluorescein and Texas Red) in the apparatus of Gordon, in order to perform assays such as a "ratiometric" immunoassay.

In regard to claim **27** which is dependent on claim 1, Gordon also discloses (column 5, lines 28-31) that the light source (8) is a coherent light source.

In regard to claim **28** which is dependent on claim 1, the apparatus of Gordon lacks that the light beam adapted provide a light spot having a diameter between 20-150 μm on the specimen. Ekins *et al.* teach (left column on pg. 1963) that as the area decreases, the signal/noise ratio increases and approaches a maximum value of 60 as the area falls below 0.01 mm^2 . A 0.01 mm^2 area has a diameter of 112 μm . Therefore it would have been obvious to one having ordinary skill in the art to provide a light spot having a diameter between 20-150 μm (e.g., 112 μm) on the specimen in the apparatus of Gordon, in order to perform a "ratiometric" immunoassay with a desired signal/noise ratio.

11. Claims 4, 5, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 5,892,577) in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967) as applied to claims 1 and 29 above, and further in view of Shih *et al.* (US 6,188,132).

In regard to claim **4** (which is dependent on claim 1) and claim **32** (which is dependent on claim 29), while Gordon also discloses (column 5, line 64 to column 6, line 3) the use of compact disc technology, the modified apparatus and method of

Gordon lacks that at least a first light source is two or more light sources. However, compact disc technology is well known in the art. For example, Shih *et al.* teach (abstract) that a compact disc laser diode package comprises two laser diodes of two different wavelengths. Further, Ekins *et al.* teach (left column on pg. 1965) that fluorescent markers may have different wavelengths for excitation maximums. Therefore it would have been obvious to one having ordinary skill in the art to provide a known compact disc laser diode package (e.g., comprising two laser diodes of two different wavelengths) in the modified apparatus and method of Gordon, in order to perform a "ratiometric" immunoassay where different wavelengths are selected for the different fluorescent marker excitation maximums.

In regard to claim 5 (which is dependent on claim 4) and claim 33 (which is dependent on claim 32), Gordon also discloses (column 6, lines 4-10) that the scanning means are adapted to perform successive scans of the specimen, the one or more light beams in each scan and in each successive scan being adapted to excite specific markers on the objects.

12. Claims 6 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 5,892,577) in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967) and Shih *et al.* (US 6,188,132) as applied to claims 5 and 33 above, and further in view of Chance *et al.* (US 3,963,351).

In regard to claim 6 (which is dependent on claim 5) and claim 34 (which is dependent on claim 33), while Gordon also discloses one detector, the apparatus and

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method of Gordon lacks adapting the one detector to detect light emitted from each marker excited by the one or more light sources in a single scan. However, multichannel fluorometers are well known in the art. For example, Chance *et al.* teach (Fig. 1) that multichannel fluorometer comprise a single detector (20) thus allowing the use of inexpensive components (column 1, lines 20-27). Therefore it would have been obvious to one having ordinary skill in the art to adapt the detector in the modified apparatus and method of Gordon multichannel fluorometry, in order to obtain an instrument with of inexpensive components.

13. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 5,892,577) in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967) as applied to claim 1 above, and further in view of Demers (WO 98/12559).

In regard to claims **15** and **16** which are dependent on claim 1, while Gordon also discloses (column 5, line 64 to column 6, line 3) a member such as a compact disc to receive and hold the specimen, the modified apparatus of Gordon lacks that the specimen has an area larger than 500 mm^2 (e.g., larger than 8000 mm^2). However, compact discs are well known in the art. For example, Demers teaches (pg. 5, third paragraph) that a compact disc is a 5.5 inch disc. A $\sim 15328 \text{ mm}^2$ area has a diameter of $\sim 140 \text{ mm}$ (5.5 inch). Therefore it would have been obvious to one having ordinary skill in the art that the $\sim 15328 \text{ mm}^2$ area member in the modified apparatus of Gordon is capable of receiving and holding specimens of $\sim 15328 \text{ mm}^2$ area or less, in order to

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perform a "ratiometric" immunoassay on specimens having an area larger than 500 mm² (e.g., larger than 8000 mm²).

14. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 5,892,577) in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967) as applied to claim 1 above, and further in view of Prasad *et al.* (US 5,912,257) and Gibbons *et al.* (US 5,846,452).

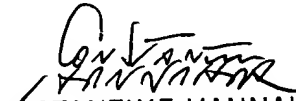
In regard to claims **19-22** which are dependent on claim 1, the modified apparatus of Gordon lacks that the scanning means further comprise deflecting means for scanning the first light beam across specimen along a radius of the circular movement of the light source or a movable deflecting means for variable deflection of the first light beam including a first mirror that is rotatable around a first axis so that the first light beam can be scanned across the specimen along a substantially circular curve and further rotatable around a second axis for variation of the radius of the circular curve. However, scanning is well known in the art. For example, Prasad *et al.* teach (column 68, line 32 to column 69, line 13) that scanning is well known in the art and comprise a rotating disc format and/or scanning mirrors. As another example, Gibbons *et al.* teach (column 21, line 50 to column 22, line 6) that two axis scanning mirror systems are commercially available. Therefore it would have been obvious to one having ordinary skill in the art to provide known equivalent scanning means (e.g., a two axis scanning mirror system) in the modified apparatus of Gordon, in order to scan the member.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (703) 308-4860. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on (703) 308-4852. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.


CONSTANTINE HANNAHER
PRIMARY EXAMINER
GROUP ART UNIT 2878

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September 22, 2003